

REMARKS

The specification is amended. Claims 1, 29 and 35 are amended. Claims 1-35 remain in the application.

The specification has been objected to. The specification has been amended according to the examiner's helpful suggestions, thereby removing the basis for the objection.

Claims 1-35 are provisionally rejected for obviousness-type double patenting over claims 1, 3-9, 11-13, 16-20, and 22-35 of co-pending application 10/214966. The applicants respectfully traverse this provisional rejection for the following reasons.

Obviousness-type double patenting requires analysis conducted according to the requirements of *prima facie* obviousness set forth in MPEP 2143, et seq. That is to say, there must be some motivation to make the modification of the tensioned rod to two rods and to "eliminate the closed arcuate handle and leave that section of the cassette solid as a stiffening portion". There must also be a reasonable expectation that the tensioning rod can be so modified. And, the modified reference must contain all elements of the provisionally rejected claims. None of these requirements has been satisfied. The sole basis for the provisional rejection is a conclusionary statement that "it would have been obvious to" modify the tensioned rod and "it would have been an obvious choice to" modify the closed arcuate handle. No support for these conclusions is given. The rejection must therefore be withdrawn.

Claims 1, 4-10, 13-17, 19, 20, and 27 are rejected for obviousness over US 6901216 ("Jusiak") in view of US 5875282 ("Jordan"). That rejection is respectfully traversed for the following reasons.

What Jordan contributes to the obviousness analysis of claims 1, 4-10, 13-17, 19, 20, and 27 is unclear, and the applicants respectfully request clarification in this regard. However, even with clarification, there is no suggestion to combine Jusiak with Jordan. Jusiak teaches away from Jordan by explicitly characterizing Jordan's cassette as being "too flimsy and difficult to insert" into the aperture of a warming unit. See Jusiak at col. 2, lines 8-10. As to specific assertions made about Jusiak in the Office Action with regard to this rejection, the applicants make the following observations.

Jusiak is referenced at col. 3, lines 27-40 and lines 47-53 as support for the assertion that element 42 is "a planar stiffener." The applicants respectfully disagree. At col. 3, lines 27-40 Jusiak identifies the element 42 as "an interconnect bar", not a "stiffener". Jusiak does not specify any function of the element 42 other than that

suggested by its title: to link the tubes 38 and 40. In the context of Jusiak's description, the interconnect bar 42 is simply one element of "an interconnected inlet/outlet system" that "is attached to the cassette in a superior manner than the individual tube method of Jordan et. al." The interconnected inlet/outlet system provides more planar space for the sheets of the cassette to seal against, which keeps tubes from separating from the seal when the cassette is handled. At col. 3, lines 47-53, Jusiak does not describe the element 42 at all, but does imply that the advantage of the interconnected inlet/outlet system of which the interconnect bar 42 is an element is that it can be handled as a single unit during assembly of the cassette. Jusiak does not describe the interconnected inlet/outlet system as a stiffener, or specify that it has the function of stiffening the cassette.

With respect to claim 4, the contention in the Office Action that "Jusiak also discloses that the stiffener has a first elongate portion extending between the first and second rails" is simply not supported by Fig. 3. Instead, this figure only shows an interconnect bar 42 linking the inlet and outlet tubes 38 and 40, which are not "rails" according to this application or Jusiak's specification. Further, according to claim 4, which inherits the limitations of claim 1 from which it is dependent, the first elongate portion of the planar stiffener is "disposed between the first sheet and the second sheet." But, according to Fig. 1, the tubes 38 and 40 are on the outside of the space enclosed by the two films 32 and 34. Fig. 3 therefore suggests that the interconnect bar 42 is also outside this space, possibly as an alternative embodiment of the interconnected inlet/outlet system shown in Fig. 1. The reference in the Office Action to Fig. 4b of Jusiak to support the rejection of claim 4 is simply not understood. Jusiak says that Fig. 4b is an alternate embodiment of Fig. 1 taken along the lines 4-4. This figure does not have any described relation to the arrangement illustrated in Fig. 3. Yet, according to the Office Action, Fig. 4b shows the "second portion protruding from the first portion in the direction of the distal end." If the interconnect bar 42 of Fig. 3 is the "first portion" of a planar stiffener, Jusiak does not show or describe the structure in Fig. 4b as "disposed between the first sheet and the second sheet," or as "protruding from the first portion in the direction of the distal end." The structure in Fig. 4b is outside of the space enclosed by the films 32 and 34. Further, the structure is positioned at the proximal end 12 of the cassette and extends away from both the proximate and distal ends of the cassette.

With respect to claim 6, the contention in the Office Action is that Jusiak discloses that the stiffener forms a handle portion. But, claim 6 does not recite that the

planar stiffener “forms” a handle. Rather, the recitation is of “a handle formed in the fluid container against the stiffener.”

Jusiak attacks the flimsiness and insertion problems of the Jordan cassette by stiffening the cassette, but not at the proximal end 12 with the interconnect bar 42. Rather, Jusiak provides the desired stiffness at the distal end 14 in the form of the tongue section 20. In this regard, Jusiak says at col. 4, lines 25-30 that “the function of the tongue section” is “to stiffen the cassette 10 and assist the user” to insert the cassette into the aperture of a warming unit. Jusiak does not assign this function to any other component or element of the cassette. The opinion that other elements such as the interconnect bar 24 act as a planar stiffener at the proximal end to stiffen the cassette is speculation, unsupported by description, illustration, facts, or reasoning.

Accordingly, the rejection of claims 1, 4-10, 13-17, 19, 20, and 27 for obviousness over Jusiak in view of Jordan should be withdrawn.

Claims 29-31 are rejected for anticipation by Jusiak. That rejection is respectfully traversed. Claim 29 recites “a handle portion formed near a proximal end of the fluid container by sandwiching a planar piece in the fluid container.” Jusiak fails to meet this element, for two reasons. First, the tongue 20 is merely described as “sealed to the cassette,” not as sandwiched by any elements of the cassette. Second, the tongue 20 is disposed on the distal end of the cassette. Accordingly, the rejection of claims 29-31 for anticipation by Jusiak should be withdrawn.

Claims 2 and 3 are rejected for obviousness over Jusiak in view of Jordan. That rejection is respectfully traversed. For reasons given above, Jusiak teaches away from being combined with Jordan. Accordingly, the rejection of claims 2 and 3 for obviousness over Jusiak in view of Jordan should be withdrawn.

Claims 11, 12, 28, 32, and 33 are rejected for obviousness over Jusiak in view of US 5205348 (“Tousignant”). That rejection is respectfully traversed for the reasons given above in respect of Jusiak’s omission of a “planar stiffener,” and for the following further reasons.

The only motivation or suggestion to combine Jusiak with Tousignant is “to provide insertion stops.” But, Jusiak’s cassette already includes insertion stops, and is therefore complete in this regard. For example, “the tubes 38 and 40 are the stopping mechanism to prevent over insertion of the cassette 10 into the warming unit.” See Jusiak at col. 5, lines 29-31. As yet a further example, the ear like projections 202 described at col. 5, lines 40-45 stop the cassette from be inserted too far. There is

therefore, no suggestion to provide “two fluid ports on the fluid container, each fluid port in fluid communication with a respective end of the fluid channel and disposed perpendicularly to the fluid container.”

Further, Tousignant’s inlet and outlet adapters 18 and 20 shown in Fig. 4 are threaded into through hole portions of a frame. At col. 7, lines 10-15, Tousignant points out an important benefit realized by this construction: “it is advantageously easy to seal the inlet and outlet adaptors to the heat transfer device 10 *without having to seal* flexible film to the inlet and outlet adaptors 18 and 20.” Similar considerations apply to the inlet and outlet adaptors in Tousignant’s Figs. 5 and 6. Jusiak, however, discloses that the inlet and outlet tubes *are sealed* to the films 32 and 34 in order to be securely positioned in the cassette. Thus, a fundamental principle of Jusiak’s construction would be violated by adoption of Tousignant’s inlet and outlet adaptors. Jusiak therefore teaches away from combination with Tousignant. Accordingly the rejection of claims 11, 12, 28, 32, and 33 for obviousness over Jusiak in view of Tousignant should be withdrawn.

Claim 18 is rejected for obviousness over Jusiak in view of US 6608968 (“Bakke”). That rejection is respectfully traversed for the reasons given above in respect of Jusiak’s omission of a “planar stiffener,” and for the following further reasons.

Bakke’s Fig. 4 shows a fluid warming envelope 16 with a “paperboard inserter 26” attached to its “rightmost end”. Inspection and comparison of Bakke with Jusiak will confirm that Bakke’s paperboard inserter 26 and Jusiak’s tongue are positioned at the same ends of their respective devices. Since Jusiak labels this end the distal end, it is fair to say that Bakke’s inserter 26 is positioned at the distal end of the envelope 16. But the planar stiffener of claim 18 inherits the “near the proximal end” limitation of claim 1, from which claim 18 depends. Further, Bakke does not teach or suggest that the inserter 26 is a stiffener, or that its function is to stiffen the fluid warming envelope 16. Instead, the inserter 26 is inserted into a warming unit to guide the fluid warming envelope 16 through the warmer “like a needle pulls a thread”, and to extend out the far end of the warmer where it is grasped to pull the fluid warming envelope into place. See Bakke at col. 6, lines 30-39. Thus, the inserter 26 is at the end of Bakke’s fluid warmer that corresponds to the *distal* ends of the fluid warming cassette of claim 18 and Jusiak’s cassette, and Bakke does not teach or suggest that the inserter 26 is a stiffener. Accordingly the rejection of claim 18 for obviousness over Jusiak in view of Bakke should be withdrawn.

Claims 21-26 are rejected for obviousness over Jusiak in view of US 4707587 ("Greenblatt"). That rejection is respectfully traversed for the reasons given above in respect of Jusiak's omission of a "planar stiffener," and for the following further reasons.

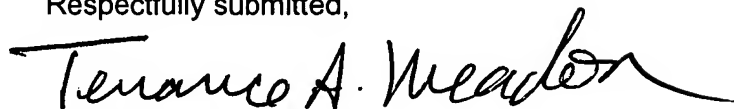
At col. 1, lines 34-45, Jusiak specifically singles out Greenblatt as representative of an undesirable warming cassette construction. Accordingly Jusiak teaches away from being combined with Greenblatt and the rejection of claims 21-26 for obviousness over Jusiak in view of Greenblatt should be withdrawn.

Claim 35 is rejected for obviousness over Jusiak in view of Tousignant, and further in view of US 4568330 ("Kujawski"). That rejection is respectfully traversed for the reasons given above in respect of Jusiak's omission of a "planar stiffener" and the lack of suggestion to combine Jusiak with Tousignant, and for the following further reasons.

Kujawski discloses a system for cooling drugs prior to perfusion onto the heart, in which a bubble trap removes bubbles from cooled fluid prior to perfusion of the heart. This reference does not address the problems of warming parenteral fluid prior to infusion into a body. There is, therefore, no suggestion to combine Kujawski with Jusiak. Moreover, Kujawski's system does not include "an injection site coupled to the outlet of the bubble trap." Accordingly the rejection of claim 35 for obviousness over Jusiak in view of Tousignant and Kujawski should be withdrawn.

It is submitted that these Remarks establish that claims 1-35 are allowable over the references of record, early notice of which is earnestly requested.

Respectfully submitted,



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Date: May 22, 2006

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